REMARKS

Applicants thank the Office for the attention accorded the present Application in the June 3, 2008, Office Action. In that Action, Claims 17-20 were rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement, Claim 15 was rejected under 35 USC §102(b) as being anticipated by Krumholz et al., Annals of Internal Medicine, 1996, Vol. 124, No. 3, Claims 16-20 were rejected under 35 USC §103(a) as being unpatentable over Krumholz et al. as applied to Claim 15 and further in view of Byrne et al. (US 5,156,849). Applicants respectfully traverse.

35 USC §112, first paragraph rejection:

The Office has rejected Claims 17-20 under 35 USC §112, first paragraph, as failing to comply with the written description requirement. The Office states that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Office states that there is no mention of exclusion of the hypertensive patients found in the instant specification. Applicants respectfully traverse.

Applicants have canceled Claim 17-20. The rejection is now moot.

In light of the amendments presented, Applicants respectfully requests that the 35 USC §112, first paragraph, rejection of Claims 17-20 be withdrawn.

35 USC §102(b) rejections:

The Office has rejected Claim 15 under 35 USC §102(b) as being anticipated by Krumholz et al., Annals of Internal Medicine, 1996, vol. 124, No. 3. The Office states that, since no details are given regarding the "single dosage unit," the language of the claim reads on two single agents, an aspirin tablet and a beta-blocker tablet in a container to be administered together such as a dosage cup. Applicants respectfully traverse.

Applicants have amended Claim 15 to limit the single dosage unit to a single tablet, a single capsule, a single caplet, a single syrup, or a single liquid. Applicants have also added new Claims 21 and 23 containing the same limitation.

Applicants note that Krumholz et al. contain no comparative teaching to incorporate aspirin and other agents together into a single dosage unit as a single tablet, a single capsule, a single caplet, a single syrup, or a single liquid.

Anticipation is established only when a single prior art reference discloses, expressly or under the principles of inherency, each and every element of the claimed invention. The Krumholz et al. reference does not disclose a single dosage unit that is a single tablet, a single capsule, a single caplet, a single syrup, or a single liquid. The Krumholz et al. reference discloses two separate and individual medications.

Where the Krumholz et al. reference fails to disclose expressly or under the principles of inherency a a single dosage unit that is a single tablet, a single capsule, a single caplet, a single syrup, or a single liquid, the Krumholz et al. reference cannot anticipate Applicant's amended Claim 15 and new Claims 21 and 23 having a single

dosage unit that is a single tablet, a single capsule, a single caplet, a single syrup, or a single liquid.

In light of the amendment and arguments presented, Applicants respectfully submit that the 35 USC §102(b) rejection of Claim 15 has been successfully traversed. Allowance is therefore requested.

35 USC §103(a) rejection:

The Office has rejected Claims 16-20 under 35 USC §103(a) as being unpatentable over Krumholz et al. as applied to Claim 15 and further in view of Byrne et al. The Office states that Krumholz et al. teach that patients treated with aspirin during hospitalization and patients prescribed beta-blockers at discharge were more likely to be treated with aspirin at discharge following acute myocardial infarction. The Office further states that the prescribed use of aspirin at discharge correlates with several indicators of better health status. The Office concludes that, motivated by these teachings of Krumholz et al. and in view of Byrne et al. who disclose a combination of a beta-adrenergic blocking agent and aspirin in a single dosage unit, it would be obvious to employ aspirin and beta-adrenergic blocking agent encompassed in a single dosage formulation to prevent secondary heart attacks.

Applicants point out that Byrne teaches beta-blockers as an antihypertensive agent but contains no teaching or suggestion for secondary prevention of a heart attack. Likewise, Krumholz et al. also contains no teaching of beta-blockers for secondary prevention of heart attacks. Applicants' specification discloses the benefit

derived from these medications after a heart attack, but point out that the beneficial effect is not the subject of the present invention. Rather, the invention seeks to remedy the failure of heart attack patients to receive and take these beneficial treatments.

Applicants' amended method claims are directed to improving upon this problem, which are directed to encouraging adherence to preventive medications following a heart attack. The data of Krumholz et al. underscores a problem with prescribing these preventive medications to patients who have suffered a heart attack, yet methods to bring about long term patient adherence/cornpliance to long term, preventive medications as claimed by Applicants were not obvious to either Krumholz or Byrne. Applicants maintain, that contrary to the Office's assertion, the combined references of Krumholz et al. and Byrne et al. do not make it obvious to employ aspirin and beta-adrenergic blocking agent in a single dosage formulation to encourage adherence to preventive medications, since adherence of a patient to preventive medications is not considered in either reference at all.

Again, Applicants direct the Office's attention to Table 2 of the study of Krumholz et al. Twenty-four percent (24%) of patients (1337/5490) who might have benefited from aspirin at hospital discharge did not receive this treatment, despite that it is acknowledged to prevent future heart attacks. More disappointing yet, sixty-six percent (66%) of patients (3614/5490) who might have benefited from beta-blockers at hospital discharge, a treatment also acknowledged to prevent recurrence of a heart attack and mortality, did not receive this treatment. **The data is not trivial.** In fact, the report of Krumholz et al. corroborates and supports Applicants' arguments and Applicants'

disclosure of the need for means and methods to encourage adherence to preventive medications by individuals who have had a heart attack.

There are numerous factors that affect adherence to preventive medication regimens. As stated in Applicants' disclosure, the problems of achieving adherence with these cardioprotective agents include the inconvenience of taking multiple dosage units over a long period of time, the lack of immediately noticeable beneficial effects from such medications which might otherwise encourage use, trivialization of common medications such as aspirin, inconvenience of the requirement to obtain some medications by prescription and some over-the-counter, unwillingness to make out of pocket purchases, and confusion in older individuals, the age group in which these medications are typically required. All of these factors are detrimental to long term compliance by a patient to a regimen of these cardioprotective agents. Thus, adherence/compliance by a patient to these preventive medications is magnified when compared to short term medications for acute medical conditions where the short term medications tend to act quickly and provide immediate and noticeable beneficial effects. Unlike the adherence/compliance problems evidenced by long term preventive medications, it is much easier to maintain patient compliance to the short term medications for acute medical conditions since the patient sees and feels the improvement in his/her medical condition in a relatively short time.

Krumholz et al. are concerned with the problem of the lack of prescribing these beneficial medications by physicians to patients upon discharge from a hospital. The above-described data confirms this. On the other hand, Krumholz et al. fail to identify

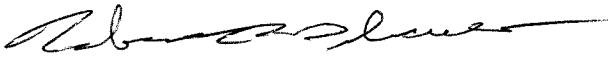
the problem from the patient's perspective, i.e. the patient's long term adherence/compliance with these medications. Byrne et al. fails to identify the problem with long term preventive measures described by Applicants in their disclosure. Byrne teaches beta-blockers as an antihypertensive agent but contains no teaching or suggestion for prevention of a heart attack in people who have already had a heart attack.

In light of the amendments and arguments presented, Applicants respectfully submit that the 35 USC §103(a) rejection of Claims 16-20 has been successfully traversed. Allowance is therefore requested.

Applicants believe that all of the pending claims should now be in condition for allowance. Early and favorable action is respectfully requested.

The Examiner is invited to telephone the undersigned, Applicant's attorney of record, to facilitate advancement of the present application.

Respectfully submitted,



Dated: 8/28/08

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